K955662

JUN 14 1996

510(k) SUMMARY

General Information

This premarket notification is for the Candela Q-Switched Alexandrite Lasers intended for use in the treatment of pigmented lesions and tattoos.

Classification:	Class II (21 CFR 878.4810 Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology)
Common Name:	Dermatology Laser, Q-Switched Alexandrite Laser
Predicate Device:	Candela Q-Switched Alexandrite Laser (Models PLTL-1 and TL-1) Cynosure Photogenica T10 Tattoo Removal Laser

Description

The Candela Q-Switched Alexandrite Lasers utilize an alexandrite rod (crystal) which emits pulsed energy at 755 nm in the near-infrared region of the electromagnetic spectrum. An electro-optical Q-Switch is employed to control pulse duration. Energy from the laser is directed to the targeted area via an optical fiber/handpiece delivery system. The Candela Q-Switched Alexandrite Lasers are designed with five major components:

1) the high voltage power supply and modulator system;
2) the optical laser head;
3) the circulator system;
4) the microprocessor-based system controller and user display panel;
5) the optical delivery system.

The Candela Q-Switched Alexandrite Lasers are equipped with safety interlock systems to protect patients and operators. Users of the device make selections from an on-board control panel to regulate operation during treatment.

Product Development Review

Design reviews conducted during development of this device verify the appropriateness of materials and design selection.

Testing

Testing of the Candela Q-Switched Alexandrite Lasers consist of component testing and functional testing of the completed laser.

Summary of Substantial Equivalence

On the basis of similarities in principles of operation, design, materials, source of energy, methods of assembly, and intended use, Candela has determined that its Q-Switched Alexandrite Lasers are substantially equivalent to the above referenced predicate devices.

No new questions of safety and efficacy are raised by the introduction of this device into commercial distribution.